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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/967,301	09/28/2001	Simon Lawrence John Stubbs	PA-0111	5224
22840	7590	10/13/2004	EXAMINER	
AMERSHAM BIOSCIENCES PATENT DEPARTMENT 800 CENTENNIAL AVENUE PISCATAWAY, NJ 08855			ROBINSON, HOPE A	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 10/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/967,301	STUBBS ET AL.	
	Examiner	Art Unit	
	Hope A. Robinson	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11, 13-18 and 26-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11, 13-18 and 26-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's response to the Office Action mailed March 31, 2004 on July 28, 2004, is acknowledged.
2. Claims 1-10, 12 and 19-25 have been canceled. Claims 26-33 have been added. Claims 11, 13-14 and 18 have been amended. Claims 11, 13-18 and 26-33 are pending and are under examination.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. The following grounds of objection/rejection are or remain applicable:

Claim Objection

5. Claims 11, 14, 26, 28 and 33 are objected to because of the following informalities:

For clarity it is suggested that claims 11, 14, 26, 28 and 33 are amended to recite "*Aequorea victoria*" instead of "*A. victoria*".

Specification

6. The specification is objected to because of the following informalities:

Art Unit: 1653

(a) The specification is objected to because trademarks are disclosed throughout the instant specification and not all of them are capitalized or accompanied by the generic terminology. The use of the trademarks such as TRIS®, for example, have been noted in this application (see page 35). It should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks. It is suggested that the specification is amended to delete "Tris-HCl" for example, and insert "TRIS® (hydroxymethyl) aminomethane hydrochloride".

(b) The specification is objected to because the sequence notation is listed as "SEQ ID No.1" (see page 8, line 20 and throughout the specification), which is improper, and should be "SEQ ID NO:1".

Correction of the above and compliance with the sequence rules is required.

Claim Rejections - 35 U.S.C. § 112

7. Claims 11, 13-18 and 26-33 are rejected under 35 U.S.C. 112, first paragraph, enablement for the reasons of record.

Response to Applicant's Arguments:

8. The response on page 13 appears to be arguing a rejection under 35 U.S.C. 112, first paragraph, written description. Applicant states that they "had possession of the

Art Unit: 1653

claimed invention at the time the instant application was filed". It is also stated that specific examples are provided on pages 31-38. The issue in this case is the breadth of the claims in light of the predictability of the art as determined by the number of working examples, the skill level artisan and the guidance presented in the instant specification and the prior art of record. This make and test position is inconsistent with the decisions of *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) where it is stated that "...scope of claims must bear a reasonable correlation to scope of enablement provided by the specification to persons of ordinary skill in the art...".

Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily and improperly extensive and undue. See *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988).

The examples provided on pages 31-38 do not address the issue raised regarding the lack of enablement for any functional analogue of GFP. It is noted that on pages 32-33 of the instant specification, a discussion/table is provided of GFP mutants, comprising single amino acid substitutions in comparison to the wildtype, however, there is no indication as to what chemical structure the vast number of GFP analogues encompassed in the claims has. Therefore, a skilled artisan has to construct any GFP analogue without direction in the instant specification and then test the analogue for biological activity. Note that the claim does not specify the particular activity the analogues has to have or whether the wildtype GFP function is retained.

It is further stated that the claims have been amended to expedite prosecution by separating the claim language for GFP with a sequence substitution at position S65 into newly added claims. The amendments made do not rectify the present situation because the issue at hand is "make and test" GFP analogues (any functional analogue) which are not supported by the instant specification. Moreover, the claims have not been amended to remove the language "any GFP analogue". Therefore, for these reasons and those stated in the Office Action mailed March 31, 2004, the rejection remains. Note that newly submitted claims have also been incorporated in this rejection, because the claim language is similar.

9. Claims 11, 13-18 and 26-33 are rejected under 35 U.S.C. 112, second paragraph for the reasons of record and the new rejections under the statute are based on the amendments made.

Response to Applicant's Arguments:

10. The response on page 15 states that the term "functional analogue" is definite because one skilled in the art of molecular biology would well understand this art recognized phrase. This argument is not persuasive. First, a search of the patented files produced thousands of references pertaining to GFP analogues thus applicant needs to be more specific with regard to this terminology. Second, there is no guidance provided in the instant specification regarding the claimed analogues. Third, a review of some of the patents indicated that a GFP analogue can be non-naturally occurring

Art Unit: 1653

synthetic nucleotides or modified naturally occurring nucleotides or a pre-protein that can be activated by cleavage to produce an active polypeptide.

In addition the response on page 15 state that Figures 5 and 6 shows the improvement of the fluorescent protein. However, the claim broadly recites that the modified GFP has a different excitation spectrum/emission compared to the wildtype and there is no recitation of any improvements. Applicant is reminded that the limitations of the specification cannot be read into the claim. Therefore the rejection over claims 11, 14 and the dependent claims hereto remains. Note also that the same language is found in new claims 26, 28, 33 and the dependent claims hereto. Thus, the rejection remains.

11. Claims 11, 15-17 and 33 are rejected is rejected under 35 U.S.C. 102(b) as being anticipated by Tsein et al. (U.S. Patent No. 6,077,707, June 20, 2000) based on any functional analogue of GFP.

Tsein et al. teach polynucleotides encoding proteins and a protein sequence that comprises SEQ ID NO:2 of the instant application (column 3 of the patent). The patented sequence is identical to the sequence set forth in SEQ ID NO:2 with the exception of some point mutations (see SEQ ID NO:4 of the patent at column 39). Tsein et al. teach more modifications to the sequence than the instant application, however, the claim recites the open language "comprising", thus other mutations/analogues are encompassed. Tsein et al. teach the following modifications :F64T, E222L and S175G (claim 11, column 39 of the patent). Tsein et al. also teach an

Art Unit: 1653

expression vector and host cell (claims 15-17, see abstract and columns 3 and 18 of the patent). Further, Tsein et al. teach a mutation at S65 that includes S65G and S65T (claim 33, see column 3 of the patent). Therefore the limitation of the claims are met by this reference.

Response to Applicant's Arguments:

12. Applicant's arguments on page 16 states that the cited prior art is not relevant based on the amendments to the claims and the newly cited material. As such the rejection of record has been withdrawn, however, a new rejection has been instituted to address the amendments made, for the reasons stated above.

Conclusion

13. No claims are allowable.

14. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

Art Unit: 1653

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hope A. Robinson whose telephone number is 571-272-0957. The examiner can normally be reached on Monday-Friday.

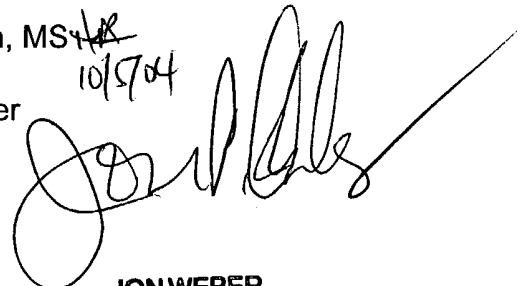
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber, can be reached at (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Hope Robinson, MS ^{HR}

Patent Examiner

10/5/04

A large, stylized handwritten signature in black ink, likely belonging to Jon Weber, is written over the printed name and title.

JON WEBER
SUPERVISORY PATENT EXAMINER